IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SHIONOGI INC. AND CONCORDIA PHARMACEUTICALS INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
ACTAVIS LABORATORIES UT, INC.,	)	
Defendant.	)	

COMPLAINT

Plaintiffs Shionogi Inc. and Concordia Pharmaceuticals Inc. (collectively, "Plaintiffs") for their Complaint against Defendant Actavis Laboratories UT, Inc. ("Actavis" or "Defendant"), hereby allege as follows.

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. §100, *et seq.*, arising from Actavis's filing of an Abbreviated New Drug Application ("ANDA") with the United States Food and Drug Administration ("FDA") seeking approval to commercially market a generic version of Plaintiffs' ULESFIA® drug product prior to the expiration of United States Patent Nos. 6,793,931 ("the '931 patent") and 7,294,342 ("the '342 patent") (collectively, "the patents-in-suit").

THE PARTIES

2. Plaintiff Shionogi Inc. ("Shionogi") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 300 Campus Drive Florham Park, NJ 07932.

3. Plaintiff Concordia Pharmaceuticals Inc. ("Concordia") is a société à responsabilité limitée (limited liability company) duly continued and validly existing under the laws of the Grand-Duchy of Luxembourg, having its registered office at 8-10 Avenue de la Gare L-1610 Luxembourg, Grand-Duchy of Luxembourg, and having a Barbados Branch with a branch address at Canewood Business Centre, 5 Canewood Industrial Park, St. Michael, Barbados, BB11005.

4. Upon information and belief, Defendant Actavis Laboratories UT, Inc. ("Actavis") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 577 Chipeta Way, Salt Lake City, UT 84108. Upon information and belief, Actavis manufactures and/or distributes generic drugs for sale and use throughout the United States, including in this judicial district. Upon information and belief, Actavis also prepares and/or aids in the preparation and submission of Abbreviated New Drug Applications ("ANDA") to the FDA.

JURISDICTION AND VENUE

5. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

6. This Court has personal jurisdiction over Actavis by virtue of the fact that, inter alia, it is a Delaware corporation and has systematic contacts with the State of Delaware.

7. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

THE PATENTS-IN-SUIT

8. On September 21, 2004, the United States Patent and Trademark Office ("USPTO") duly and lawfully issued the '931 patent, entitled "Ectoparasite Asphyxiator

Compositions and Methods for their Applications" to Summers Laboratories, Inc. ("Summers") as assignee of the inventor Michael J. Precopio. A copy of the '931 patent is attached hereto as Exhibit A.

9. On November 13, 2007, the USPTO duly and lawfully issued the '342 patent, entitled "Ectoparasite Asphyxiator Compositions and Methods for their Applications" to Summers as assignee of the inventor Michael J. Precopio. A copy of the '342 patent is attached hereto as Exhibit B.

10. On or about December 26, 2007, Summers assigned its rights to the '931 and '342 patents to Sciele Pharma ("Sciele"). On or about September 1, 2008, Shionogi acquired Sciele, including Sciele's rights to the '931 and '342 patents. Shionogi is the current assignee of the '931 and '342 patents. On or about May 6, 2013, Shionogi exclusively licensed its rights to the '931 and '342 patents to Concordia.

THE ULESFIA® DRUG PRODUCT

11. Shionogi holds an approved New Drug Application ("NDA") under Section 505(a) of the Federal Food Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 355(a), for ULESFIA® (Benzyl Alcohol) Lotion, 5%. ULESFIA® was approved for the topical treatment of head lice infestation in patients 6 months of age and older on April 9, 2009.

12. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the patents-in-suit are listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to ULESFIA®. The claims of the patents-in-suit cover, inter alia, compositions and methods for treating ectoparasite infestations on animal skin and hair.

ACTS GIVING RISE TO THIS ACTION

13. Pursuant to Section 505 of the FFDCA, Actavis filed ANDA No. 209212 ("Actavis's ANDA") seeking approval to engage in the commercial use, manufacture, sale, offer for sale or importation into the United States of Benzyl Alcohol Lotion, 5% ("Actavis's Proposed Product"), before the patents-in-suit expire.

14. In connection with the filing of its ANDA as described in the preceding paragraph, Actavis has provided a written certification to the FDA, as called for by Section 505 of the FFDCA, alleging that the claims of the patents-in-suit are invalid, unenforceable, and/or will not be infringed by the activities described in Actavis's ANDA.

15. On or about June 2, 2016, Plaintiffs received written notice of Actavis's ANDA certification ("Actavis's Notice Letter"). Actavis's Notice Letter alleged that the claims of the '931 and '342 patents are invalid, unenforceable, and/or will not be infringed by the activities described in Actavis's ANDA. Actavis's Notice Letter also informed Plaintiffs that Actavis seeks approval to market Actavis's Proposed Product before the '931 and '342 patents expire. In the Notice Letter, Actavis did not assert non-infringement of claims 1-2, 4-6, 8-17, 20-23, 26, 28-29 and 32-38 of the '931 patent or claims 1 and 3-16 of the '342 patent. Actavis therefore concedes that Actavis' Proposed Product would infringe those claims of the '931 and '342 patents, respectively, if used, manufactured, sold, offered for sale, or imported into the United States.

COUNT I: INFRINGEMENT OF THE '931 PATENT

16. Plaintiffs repeat and reallege the allegations of the preceding paragraphs as if fully set forth herein.

17. Actavis's submission of its ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation into the United States of Benzyl Alcohol Lotion, 5%, prior to the expiration of the '931 patent, constituted infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

18. There is a justiciable controversy between the parties hereto as to the infringement of the '931 patent.

19. Unless enjoined by this Court, upon FDA approval of Actavis's ANDA, Actavis will infringe the '931 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing into the United States, and/or selling Actavis's Proposed Product in the United States.

20. Unless enjoined by this Court, upon FDA approval of Actavis's ANDA, Actavis will induce infringement of the '931 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing into the United States, and/or selling Actavis's Proposed Product in the United States. On information and belief, upon FDA approval of Actavis's ANDA, Actavis will intentionally encourage acts of direct infringement with knowledge of the '931 patent and knowledge that its acts are encouraging infringement.

21. Unless enjoined by this Court, upon FDA approval of Actavis's ANDA, Actavis will contributorily infringe the '931 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing into the United States, and/or selling Actavis's Proposed Product in the United States. On information and belief, Actavis has had and continues to have knowledge that Actavis's Proposed Product is especially adapted for a use that infringes the '931 patent and that there is no substantial noninfringing use for Actavis's Proposed Product.

22. Plaintiffs will be substantially and irreparably damaged and harmed if Actavis's infringement of the '931 patent is not enjoined.

23. Plaintiffs do not have an adequate remedy at law.

24. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT II: INFRINGEMENT OF THE '342 PATENT

25. Plaintiffs repeat and reallege the allegations of the preceding paragraphs as if fully set forth herein.

26. Actavis's submission of its ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation into the United States of Benzyl Alcohol Lotion, 5%, prior to the expiration of the '342 patent, constituted infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

27. There is a justiciable controversy between the parties hereto as to the infringement of the '342 patent.

28. Unless enjoined by this Court, upon FDA approval of Actavis's ANDA, Actavis will infringe the '342 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing into the United States, and/or selling Actavis's Proposed Product in the United States.

29. Unless enjoined by this Court, upon FDA approval of Actavis's ANDA, Actavis will induce infringement of the '342 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing into the United States, and/or selling Actavis's Proposed Product in the United States. On information and belief, upon FDA approval of Actavis's ANDA, Actavis will intentionally encourage acts of direct infringement with knowledge of the '342 patent and knowledge that its acts are encouraging infringement.

30. Unless enjoined by this Court, upon FDA approval of Actavis's ANDA, Actavis will contributorily infringe the '342 patent under 35 U.S.C. § 271(c) by making, using, offering

to sell, importing into the United States, and/or selling Actavis's Proposed Product in the United States. On information and belief, Actavis has had and continues to have knowledge that Actavis's Proposed Product is especially adapted for a use that infringes the '342 patent and that there is no substantial noninfringing use for Actavis's Proposed Product.

31. Plaintiffs will be substantially and irreparably damaged and harmed if Actavis's infringement of the '342 patent is not enjoined.

32. Plaintiffs do not have an adequate remedy at law.

33. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that the Court grant the following relief:

(A) A Judgment that Actavis has infringed the '931 and '342 patents by submitting ANDA No. 209212 to the FDA;

(B) A Judgment that Actavis's making, using, selling, offering to sell, or importing into the United States Actavis's Proposed Product will infringe one or more claims of the '931 and '342 patents;

(C) An Order that the effective date of FDA approval of ANDA No. 209212 be a date which is not earlier than the expiration date of the '931 and '342 patents, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

(D) Preliminary and permanent injunctions enjoining Actavis and its officers, agents, attorneys and employees, and those acting in privity or concert with them, from making, using, selling, offering to sell, or importing into the United States Actavis's Proposed Product, or any other product infringing any claim of the '931 or '342 patent, or from actively inducing or

contributing to the infringement of any claim of the '931 or '342 patent, until after the expiration of the '931 and '342 patents, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

(E) To the extent that Actavis has committed any acts with respect to the inventions claimed in the '931 and '342 patents, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), that Plaintiffs be awarded damages for such acts;

(F) If Actavis engages in the commercial manufacture, use, importation into the United States, sale, or offer for sale of Actavis's Proposed Product prior to the expiration of the '931 and '342 patents, a Judgment awarding damages to Plaintiffs resulting from such infringement, together with interest;

(G) Attorneys' fees in this action as an exceptional case pursuant to 35 U.S.C. § 285;

(H) Costs and expenses in this action; and

(I) Such further and other relief as this Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Jack B. Blumenfeld

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